K123419

510(k) Summary
510(k) Number K12

AFP Imaging Corporation
dba ImageWorks
250 Clearbrook Road, Suite 240
Elmsford, NY 10523 USA
914.592.6100 - Voice
800.592.6666 - Toll Free
914.592.6148 – Fax
Prepared by: James Johnson, Director of Engineering
Date Prepared: 23 October 2012

DEC 2 7 2012

1. Device Name

Proprietary Name:	**EVA Select Digital Dental Imaging System**
Common/Usual Name:	Accessory to Extra oral X-Ray System
Classification Name:	Extra oral Source X-Ray System Accessory
Classification Code:	MUH

2. PREDICATE DEVICES

- AFP Imaging EVA Digital Dental Imaging System K030647
- Midmark Clearvision K112380
- Takara Belmont Belsensor Gold K102456

3. Intended Use

The EVA SELECT Digital Dental Imaging System is intended to be used with standard dental X-ray systems and computer stations for system operation, archive data storage, digital dental image input capture and enhancement, and patient data and support.

4. Device Description

The EVA SELECT System (previously named the EVA System) has been modified to incorporate a new sensor component. The proposed EVA System is essentially identical in intended use and fundamental technology to the parent EVA Digital Dental Imaging System. The modifications are limited to changing the sensor from a proprietary design to a commercially available sensor which is already used in at least 2 devices with pre-market clearances (K112380 and K102456). As with the original EVA Sensor, the CMOS sensor when exposed to radiation uses a scintillator to indirectly capture the image in the form of a charge pattern on its surface. The resulting electronic output signals are digitized and sent to a computer via a USB interface. The images are then available for display on a computer monitor screen.

6. Substantial Equivalence and Technological Characteristics

Description Information	EVA K030647	Clear Vision K112380	BelSensor Gold K102456	EVA SELECT
Manufacturer	AFP Imaging	Mid Mark	Takara Belmont	AFP Imaging dba ImageWorks
Intended Use	The EVA Digital Dental Imaging System is intended to be used with standard digital dental X-ray systems and computer stations for system operation, archive data storage, input capture and enhancement, and patient data and support.	ClearVision is intended to be used by dentists and other qualified professionals for producing diagnostic x-ray radiographs of dentition, jaws and other oral structures.	The BelSensor GOLD is a USB-driven digital sensor which is intended to acquire dental intra-oral radiology images. The BelSensor GOLD shall be operated by healthcare professionals, who are educated and competent to perform the acquisition of dental intra-oral radiographs. The BelSensor GOLD can be used either in combination with special positioning devices to facilitate positioning and alignment with the x-ray beam or it may also be positioned by hand with the assistance of a patient.	The EVA SELECT Digital Dental Imaging System is intended to be used with standard dental X-ray systems and computer stations for system operation, archive data storage, digital dental image input capture and enhancement, and patient data and support.
Number of Sensors	2 Sizes	2 Sizes	2 Sizes	2 Sizes
Sensor Sizes (mm)	19.92mm x 29.97 mm 36.03 mm x 25.83 mm	19.95 mm x 30.02 mm 36.00 mm x 25.99 mm	19.95 mm x 30.02 mm 36.00mm x 25.99 mm	19.95 mm x 30.02 mm 36.00 mm x 25.99 mm
Pixel Size	30 µm	19 µm	19 µm	19 µm
Resolution	Resolution theoretical(optical) = 16.67 lp/mm Resolution actual = 12 lp / mm	26.3 lp/mm (theoretical) 18.0 lp/mm (actual)	26.3 lp/mm (theoretical) 18.0 lp/mm (actual)	26.3 lp/mm (theoretical) 18.0 lp/mm (actual)
Technology	CMOS	CMOS	CMOS	CMOS
Scintillation	GadOx	CsI	CsI	CsI
Interface with PC	USB	USB	USB	USB
Power source	5 V (USB)	5 V (USB)	5 V (USB)	5 V (USB)
Gray Shades	4096	4096	4096	4096
Cable Length	2 m	3 m	3 m	3 m

7. Safety and Effectiveness, comparison to predicate device.

The results of clinical image inspection, bench, and test laboratory results indicates that the new device is as safe and effective as the predicate devices. Clinical images collected demonstrate equal or better image quality as compared to our predicates.

8. Summary of Bench Testing Conducted:

Line pair phantoms and step wedge images were evaluated. IEC Standards were employed for: Electrical Safety and Electromagnetic Compatibility standards compliance. Risk Analysis and Software validation was conducted in accordance with FDA guidance documents.

9. Summary of Clinical Testing:

Clinical images were acquired and evaluated by a qualified dentist who concluded the images from the new panel are as good as or better than the images acquired with the predicate panel.

10. Conclusion:

After analyzing bench, image, and external laboratory testing to applicable standards, it is the conclusion of AFP Imaging Corporation that the EVA SELECT is as safe and effective as the predicate devices, have few technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

AFP Imaging Corporation
c/o Daniel Kamm, P.E.
Kamm & Associates
8870 Ravello Ct.
NAPLES FL 34114

December 27,2012

Re: K123419
Trade/Device Name: EVA Select Dental Imaging System
Regulation Number: 21 CFR 892.1800
Regulation Name: Extraoral Source X-ray System
Regulatory Class: Class II
Product Code: MUH
Dated: Oct. 29, 2012
Received: Nov. 6, 2012

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Michael D. O'Hara

Janine M. Morris
Director
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123419

Device Name: EVA Select Digital Dental Imaging System

Indications for Use: The EVA SELECT Digital Dental Imaging System is intended to be used with standard dental X-ray systems and computer stations for system operation, archive data storage, digital dental image input capture and enhancement, and patient data and support.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Michael D. O'Hara

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) K123419